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בקשה לפטנט

Application for Patent

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אני , (שם המבקש, מענו - ולגבי גוף מאוגד - מקום התאגדותו) I (Name and address of applicant, and, in case of body corporate place of incorporation)

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Place of Incorporation: Delaware

ששמה הוא <u>Assignment</u>	העברה	בעל אמצאה מכח
Of an invention, the title of which is		Owner, by virtue of
	מערכת לחיבור בין כלי דם	(בעברית) (Hebrew)
Anastomotic Connection System		(באנגלית) (English)

Hereby apply for a patent to be granted to me in respect therof מבקש בזאת כי ינתן לי עליה פטנט - בקשת חלוקה - בקשת פטנט מוסף *דרישה דין קדימה Application of Division Application for Patent Addition Priority Claim מדינת האגוד מבקשת פטנט לבקשה/לפטנט* מספר/ סימן תאריד Convention Country from Application to Patent/Appl. Number/Mark Date PCT/IL00/00611 2000 ספטמבר 28 _____ מסי **PCT** Dated מיום Dated PCT/IL01/00074 2001 ינואר 25 **PCT** 2001 מרץ 200 **PCT** ייפוי כחל כללק מיוחד - רצוף בזה / עוד יוגש PCT/IL01/00266 P.O.A: general / individual - attached / to be filed later 124694 filed in case _____ _הוגש בעניין המען למסירת הודעות ומסמכים בישראל**שניטר ושות׳** עורכי פטנטים בעיים Address for Service in Israel רחי בזל 16 פיית 49002 פיית, 49002 מיית, 49002 עבור המבקש, חתימת המבקש שנת 2001 יוני בחודש היום Signature of Applicant Of the year Of This לשימוש הלשכה For Office Use פנסטר ושותי עורכי פטנטים בע"מ

088/02291

טופס זה, כשהוא מוטבע בחותם לשכת הפטנטים ומושלם מספר ובתאריך ההגשה, הינו אישור להגשת הבקשה שפרטיה רשומים לעיל. This form, impressed with the Seal of the Patent Office and indicating the number and date of filing, certifies the filing of the application, the particulars of which are set out above.

מערכת לחיבור בין כלי דם

Anastomotic Connection System

By-Pass, Inc. c:088/02291

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ANASTOMOTIC CONNECTION SYSTEM

RELATED APPLICATIONS

The present application is related to the following PCT publication and applications, PCT/IL01/00266, WO 01/41624, PCT/IL01/00074, WO 00/56226 and WO 00/56228 the disclosures of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to the field of creating anastomotic connections, especially between blood vessels.

BACKGROUND

Several types of methods of connecting a graft to a blood vessel have been previously suggested, including, for example creating an anastomotic connection using a single connector and creating a connection using a plurality of surgical clips. In a side to end connection, an incision or a hole is usually formed in the side vessel and the end of the end vessel attached to the incision or hole.

After the anastomotic connection is completed, one or both of the blood vessels may change in diameter, for example, a saphaneous vein naturally increases in diameter, due to the increase pressure inside the vein. In addition, forces acting on the side blood vessel may extend any incision or hole formed in the vessel, potentially causing a leakage of blood.

SUMMARY OF THE INVENTION

An aspect of some embodiments of the invention relates to an anastomotic connector, a set of clips for forming an anastomotic connection and/or an anastomosis delivery system, having a special design, for example a reinforcement and/or a motion limiter, at parts that correspond to high tension portions of the anastomotic connection, to prevent damage to a target blood vessel. Thus, in one embodiment of the invention, some clips are more loosely coupled (if at all coupled) than other clips.

In an exemplary embodiment of the invention, the anastomotic connection is characterized by including a plurality of tissue attachment points, for example spikes of a connector or individual clips, which attachment points can move relative to each other, for example, expand. In an exemplary embodiment of the invention, pairs of attachment points that are at ends of an incision are coupled together to reduce their relative motion. In the example of clips, a double, angled, clip is optionally provided for the incision ends.

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In an alternative embodiment of the invention, each tissue attachment point is defined by an apertured segment and the apertured segments are not substantially distorted when the connector as a whole is distorted, for example to increase in radius.

An aspect of some embodiments of the invention relates to an anastomotic connection adapted to conform to blood vessel geometry and/or allow changes in blood vessel diameter. In an exemplary embodiment of the invention, the connector comprises a ring that interconnects a plurality of substantially independent clip elements. A virtual ring is defined by the clamp points of the clips (when closed). In an exemplary embodiment of the invention, the virtual ring and the ring are not congruent rings. Optionally, the rings are offset in the plane of the ring and/or along a direction perpendicular to the plane of the ring. Alternatively or additionally, the rings have different diameters. Alternatively or additionally, the ring has a different degree of obliqueness and/or orientation than the virtual ring.

In an exemplary embodiment of the invention, the differences in ring geometries cause the clips to be twisted relative to the ring. Alternatively or additionally, each clip can move separately, so that the clamp points define a non-planar ring that better conforms to the side blood vessel geometry. Alternatively or additionally, if the blood vessels change in geometry, the degree of twisting of each clip can change. In an exemplary embodiment of the invention, the clips are designed to have a preferential twist direction, thus encouraging a desired blood vessel conformance. In some embodiments of the invention, the interconnection ring provided a minimum degree of flexibility while still imposing an flexible limitation on the relative positions and/or orientations of the clip elements. Optionally, the ring is thin or twist joints interconnect the clips and the ring, to allow the twisting.

In an exemplary embodiment of the invention, the clips are interconnected by straight segment. Alternatively, the clips are interconnected by bent segments, which allow radial expansion and/or support twisting.

In an exemplary embodiment of the invention, an anastomotic connector comprises a plurality of clips and a plurality of tissue pullers that pull vascular tissue into the clip.

In another exemplary embodiment of the invention, the connector is a base-plate type connector in which the base plate is flexible to allow conformance of base plate to the side blood vessel.

In an exemplary embodiment of the invention, the individual clips or portions of the base plate, even if apertured, do not substantially distort when the connector as a whole is distorted.

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An aspect of some embodiments of the invention relates to a ring anastomotic connector in which a resilient ring interconnects a plurality of independently-patent tissue holders, for example clips or hook tips each of which can clamp together two blood vessel walls, against force. In an exemplary embodiment of the invention, the ring defines a desired anastomosis radius. The ring may be resiliently or plastically deformed to support a greater radius if the blood vessel expands. Alternatively or additionally, the ring may resiliently urge the radius towards a certain size. Different resiliency values may be used for different blood vessels, in which different post-bypass behaviors are expected. In some embodiments of the invention, a similar design is used for hole closure devices, for example to allow for distortion of the blood vessel.

An aspect of some embodiments of the invention relates to clips including an aperture for the passage of one or two tissue pullers. The clips may include one or more spikes to engage blood vessel tissue. Optionally, the aperture also accommodates a clip holder for holding the clip during tissue pulling.

Alternatively or additionally, the aperture is used to hold the clip in place during deployment or for guiding a clip deforming element.

An aspect of some embodiments of the invention relates to a puller-pair geometry, in which two pullers, each designated for a different blood vessel are arranged to be coaxial. In an exemplary embodiment of the invention, one puller fits along a slot defined in the other puller.

In an alternative embodiment of the invention, an anastomotic connector comprises an apertured base, through which a plurality of hooked pullers extend. Optionally, each aperture has associated therewith one or more tabs that cooperates with a geometry of the puller to prevent disengagement of the puller once the puller is retracted through the aperture.

An aspect of some embodiments of the invention relates to a base-plate type anastomosis connector that allows sutures to be added to correct defects in an anastomosis. In an exemplary embodiment of the invention, the base plate is apertured and/or is sparse (i.e., does not fill space), to allow room for insertion of a needle therethrough. Alternatively or additionally, the base plate is made of a piercable material. Optionally, the base plate is flexible to allow distortion of the base plate and/or anastomotic connection during stitching.

An aspect of some embodiments of the invention, relates to the design of a puller engagement element. In an exemplary embodiment of the invention, the element includes a tab that prevents disengagement of the puller once the puller is retracted. In an exemplary embodiment of the invention, the tab has curved tab geometry, to allow a greater length of a

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tab in a limited space. The length, coupled with a sufficient tab thickness and/or metallurgical treatment, optionally provide sufficient strength, resilience and/or range of motion to the tab. One, two or more tabs may be provided.

An aspect of some embodiments of the invention relates to a puller engagement element that includes a bar, which bar is engaged by a hook tip of the pullers. In an exemplary embodiment of the invention, the aperture is defined as a pair of openings separated by a short segment, such as a bar. The puller extends through one opening and, when retracted, the tip of the hook of the puller extends into the other opening.

An aspect of some embodiments of the invention relates to a method of holding a base part of an anastomotic connector during deployment. In an exemplary embodiment of the invention, at least two hinged tabs hold the base portion against a delivery system. When the base portion is to be released, the tabs are released and allowed to rotate, so they do not block the motion of the base plate. In an exemplary embodiment of the invention, the tabs are held at an outer section thereof and prevented from rotation by an element that hooks an aperture nearer an inner section thereof. The tabs are released by retracting the element so that it pulls through the aperture and releases it.

An aspect of some embodiments of the invention relates to an extension mechanism for an anastomosis delivery and/or hole punching system. In an exemplary embodiment of the invention, a same system can be used for open chest, for keyhole and/or for endoscopic surgery. In an exemplary embodiment of the invention, the delivery system includes at least one axial rod (which may be hollow) that is advanced, retracted and/or rotated to effect the operation of the system. In an exemplary embodiment of the invention, the rod(s) is formed from two parts that interlock to provide the required coupling. To extend the delivery system, the two parts are disconnected and an extension piece having matching interlock mechanism inserted. Thus, for example, an anastomosis delivery system in which the pullers are retracted into a base part has the pullers coupled to an initial rod and an extension rod coupled to the initial rod. The pulling and sequencing mechanism is optionally located in the delivery system handle.

In an exemplary embodiment of the invention, an anastomosis delivery mechanism is provided as a modular capsule that can be attached to the delivery system and/or an extension. Optionally, a same drive mechanism is provided for punching and for anastomosis delivery, so that a same device can be used for both, except that a punching capsule is replaced by a

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delivery capsule. Both capsules, for example, may be activated by retraction and/or rotation of the rod.

Optionally, the extension is flexible, rather than rigid as in other embodiments. Optionally, a channel for a camera and/or light source is provided in the extension, for assisting endoscopic surgery.

In an exemplary embodiment of the invention, the delivery system is a split system in which retraction of the rod causes the system to split and release a delivered blood vessel. In an exemplary embodiment of the invention, the end of the delivery system is coupled to the extension piece in a manner that keeps the two connected even when splitting is performed, for example, via the rod interlock or by providing an interlock between the bodies of the end and the extension.

There is thus provided in accordance with an exemplary embodiment of the invention, a n anastomotic connector comprising:

a plurality of clip segments interconnected by a plurality of twistable resilient segments. Optionally, said segments are bendable out of a plane defined by said clip segments.

There is also provided in accordance with an exemplary embodiment of the invention, an anastomotic connector comprising:

a plurality of clip segments each defining a clip contact area where opposite sides of the clip engage tissue, interconnected by a plurality of attachment segments, wherein said attachment segments define a first circumference and said contact areas define a second circumference and wherein said two circumferences are not on a same plane.

BRIEF DESCRIPTION OF THE FIGURES

Non-limiting embodiments of the invention will be described with reference to the following description of exemplary embodiments, in conjunction with the figures. The figures are generally not shown to scale and any measurements are only meant to be exemplary and not necessarily limiting. In the figures, identical structures, elements or parts which appear in more than one figure are preferably labeled with a same or similar number in all the figures in which they appear, in which:

- Fig. 1 illustrate an anastomosis clip set mounted on a clip deployment system that includes a plurality of pullers, in accordance with an exemplary embodiment of the invention;
- Fig. 2 illustrates a delivery system for elastic clips, in accordance with an exemplary embodiment of the invention;

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- Fig. 3 illustrates a portion of a delivery system for plastic deforming of clips, in accordance with an exemplary embodiment of the invention;
- Fig. 4 illustrates an alternative clip system in which clips face inwards rather than axially, in accordance with an exemplary embodiment of the invention;
- Fig. 5 illustrates an alternative clip design, in accordance with an exemplary embodiment of the invention;
- Figs. 6A and 6B illustrate a clip-ring connector, in accordance with an exemplary embodiment of the invention;
- Figs. 7A-7E illustrate apertured-base anastomotic connectors, in accordance with an exemplary embodiment of the invention; and
 - Figs. 8A-8D illustrate an extendible delivery system in accordance with an exemplary embodiment of the invention.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

Fig. 1 illustrate an anastomosis clip set 101 mounted on a clip deployment system 100 that includes a plurality of pullers 118 and 120, in accordance with an exemplary embodiment of the invention.

An anastomotic connection is performed by inserting pullers 118 into an opening in a target side vessel and pulling the vessel wall into a plurality of clips 102 using the pullers. The tissue of an end vessel is also pulled into the clip using the same or other pullers. The clips are then closed, locking together the two blood vessels. Various configurations of pullers and blood vessels have been suggested in pervious applications of the present assignee. In the particular example shown, a pair of pullers may be provided for each clip, although not shown for clarity.

In an exemplary embodiment of the invention, one or both of the pullers are provided through an aperture 104 formed in a body 106 of each clip. In Fig. 1, not all clips 102 have pullers, while this is done for clarity of presentation, in some embodiments of the invention, not all clips are actually provided with one or both pullers.

In the particular embodiment shown, the clips rest on a holder 112 comprising an inner ring 116 and an outer ring 114. Closing the clips can be achieved, for example, by retracting the clips, for example using additional pullers (not shown)on either side of the clip. Alternatively, the pullers are used to close the clips. In one embodiment of the invention, the hooked tips of the pullers urge the tissue forcefully against body 106 of clip 102, so as to cause

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it to close. Alternatively, the puller tip may be wide enough to directly apply force to clip body 104. The puller may then be distorted (open) as it is further pulled out or it may be cut.

In an exemplary embodiment of the invention, the pullers are side by side, for example pullers 118 and 120. Alternatively, the pullers are coaxial, for example, a puller 122 has a slotted shaft 124 through which a puller 118 can fit. A tip 126 as shown is wide enough to distort clip 102.

The ends of the clips are optionally serrated, for example having four teeth 108 and 110 on either side of the clip. Fewer teeth (e.g., two) may be provided. Optionally, the teeth interlock (not shown). Alternatively, spikes that penetrate the vessel tissue to a significant depth, are provided at the ends of the clips.

Alternatively to plastically deforming the clips, in an exemplary embodiment of the invention, the clips are self-deforming, for example, being elastic, super elastic of shapememory. Fig. 2 illustrates a delivery system 200 for elastic clips, in accordance with an exemplary embodiment of the invention. Only a single clip and pullers is shown, for clarity, however, typically more than one clip is deployed at a time. An exemplary elastic clip 202, that can have the same geometry as clip 102 (e.g., with an aperture 206), except that it is self-deforming, is restrained from closing by a tab 212 and a tab 210. The tabs may hold the clip from its ends, for example from inside its aperture 206 as shown for tab 212 and/or from outside, for example as shown for tab 210. Alternatively the clip may be held from the side (and optionally released by rotation of the holder).

In an exemplary embodiment of the invention, a plurality of tabs 210 is mounted on an outer ring 214 and a plurality of tabs 212 is mounted on an inner ring 216. In use, pullers 122 and 118 (or only one puller) are used to retract tissue into clip 202 and then inner ring 216 is retracted and/or outer ring 214 advanced, to release the clip to self-deform to a closed configuration.

Fig. 3 illustrates a delivery system 300 for plastic deforming of clips 102, in accordance with an exemplary embodiment of the invention. Two clip holders 304 and 306 are shown for engaging the sides of clip 102. As shown, the holders are shaped like pullers and also pass through aperture 105. Optionally, the holders separate the two pullers. Alternatively or additionally, the holders are provided from outside of clip 102. In use, after pullers 118 and 120 pull tissue into clip 102, holders 304 and 306 retract the clip, which is bent by as the clip is longer (in its open configuration) than a space between a pair of rings 314 and 316 that hold it. Alternatively or additionally, the two rings advance towards each other to squeeze the clip

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shut. Optionally, the rings do not change in diameter, and supported on shafts that are not coaxial, so that when one ring is rotated the spacing between the rings changes.

Holders 304 and 306 are optionally removed by further retraction that deforms the shape of their tips.

Fig. 4 illustrates an alternative clip system 400 in which a plurality of clips 402 face inwards rather than axially. In one example, clips 402 are always in a closed configuration as shown and the pullers (not shown), which are optionally provided through apertures 404 of clips 402, pull the tissue past one or more spikes 408 of clips 402. Alternatively, clips 402 are self-deforming and the pullers retract the tissue while the clips (but optionally not the spikes) are flat. The clips are then released to self deform to the configuration shown in Fig. 4. Optionally, a base ring 410 is attached to the clips and controls their relative positions and/or holds down one side of the clips. Optionally the ring is detached after the anastomosis is completed. Alternatively ring 410 remains in the body, the ring can be deformable, for example, as described below. In one example, a plurality of clip holders (not shown) urge clips 402 against ring 410 during deployment. Other clip orientations can also be provided.

Fig. 5 illustrates an alternative clip design 502, in accordance with an exemplary embodiment of the invention. One or more spikes 508 of clip 502 can be, for example curved (as shown) or re-curved (as shown in Fig. 4). The size and shape of an aperture 506 in a body 504 of the clip can also vary. As shown below in Fig. 7, in some cases, the aperture is split into two parts.

Figs. 6A and 6B illustrate a clip-ring connector 600, in accordance with an exemplary embodiment of the invention.

Connector 600 comprises a plurality of individually patent clip elements 602 that are interconnected by a ring of short segments 616. In the particular embodiment shown, the clips are all of one type, but this is not essential. As shown the clips comprise an elliptical body 604 having two inward pointing extensions 608 and 610 that terminate in contact surfaces 612 and 614. Alternative clip designs, such as using spikes, using a unenclosed body or a non-elliptical body, may also be provided. Optionally, an aperture 606 defined by enclosing body 604 serves as a channel for one or more tissue pullers.

In an exemplary embodiment of the invention, a clip 602 is closed by bending, while the extensions which optionally also bend, meet at their tips, at surfaces 612 and 614. Fig. 6B shows a side view of such a closed clip. The curved shape can be achieved, for example, if the clip is self-deforming. A device similar to that of Fig. 2 is optionally used for deployment

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In an exemplary embodiment of the invention, extensions 608 and 610 are designed to meet off-center from ring 610, along a virtual ring 618, which can have a varying diameter. If spikes are used instead of extensions, the spikes optionally include tissue stops to ensure that the clamped tissue meets at virtual ring 618. Fig. 6B shows the contact between surfaces 612 and 614.

In an exemplary embodiment of the invention, the closed clips twist and/or bend around ring 616, allowing the connector as a whole to better adapt to a blood vessel diameter change and/or to better conform to the surface of the side vessel and prevent over-straining of the side vessel.

Optionally, ring 616 is extendible, for example as described below if the segments are curved rather than straight.

Figs. 7A-7E illustrate apertured-base anastomotic connectors, in accordance with an exemplary embodiment of the invention. In such a connector, a plurality of pullers 704 pull tissue towards a base plate 702 and then the pullers are sheared leaving only their tips 706 urging the tissue against the base plate. Both tips and base plate remain in the body. It should be noted, however, that the various features described below (e.g., flexible base plate) may also be applied towards clip-based devices (e.g., as a flexible clip ring), in which the tips do not remain in the body.

Fig. 7A illustrates a hybrid base-plate connector 700 in which some of the apertures of the base plate are provided as individual elements and some as mini-base plates including two or more apertures. The elements are optionally held together by the delivery system (e.g., the continuation of the pullers may meet) and/or by the blood vessel, after deployment. In the embodiment shown, a plurality of individual-aperture plates 712 each include an aperture 716 and a pair of tabs 718 to control the passage of a puller 704 therethruogh. At the ends of the connector, a larger base-plate 714 having two apertures is provided. In an exemplary embodiment of the invention, the connector is inserted through an incision in a blood vessel. The larger base plate is provided to prevent or reduce relative motion of two tissue attachment points at the ends of the incision, which might extend the incision and cause a blood leak. As the connection process causes stress in the vessels, in some embodiments, the aperture plates are not interconnected, but the guides for retracting the pullers are interconnected to prevent motion at the ends of the incision.

In the exemplary embodiment shown, each puller 704 comprises a shaft 710 having protrusions 708 that match tabs 718. An optional puller shearing point (e.g., a thinning) is not

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shown. As described in other applications of the present assignee, the puller includes a tab that prevents the puller tip from falling out of the aperture. The tab cannot pass by the cutting plate (744, Fig. 7C) so further attempted retraction of the puller tears the puller, at the shearing point, which is, for example, a thinner portion of the puller shaft.

Optionally, the other aperture-plates are also interconnected, for example using a resilient spring which will allow relative radial and/or twisting motion of the aperture plates. An exemplary such base plate 720 is shown in Fig. 7B.

Base plate 720 comprise a plurality of apertures element 722 interconnected by resilient spring segments 726. Optionally, at the ends of the ring, relatively rigid connection segments 724 are provided.

Each aperture element 722 optionally comprises a bar 730 that separates the aperture into two parts, a passage aperture 734 for passage of the puller and a hook aperture 736 for receiving the tip of the puller. In an exemplary embodiment of the invention, the tip of the puller passes past the plane of bar 730. Optionally, the hook aperture is larger than the passage aperture, to compensate for freedom of movement of the tip.

In an exemplary embodiment of the invention, one or more tabs 728 is provided to engage protrusions 708 and prevent the puller from falling out once it is retracted past the tabs. After deployment, the tabs themselves, or the tabs backed by the vessel wall, possibly prevent reverse motion of the tabs. Optionally, the tabs are curved, to allow a longer length in the limited space of aperture element 722.

In an exemplary embodiment of the invention, base plate 720 is made sparse to allow an anastomosis connection to be enhanced or corrected by passing a manual suture.

Fig. 7C shows base plate 720 in a radially contracted configuration, with spring segment 726 bend to allow aperture elements 722, which are generally not affected by the radial compression, to be closer together. Base plate 720 may be elastically or plastically deformed. In an exemplary embodiment of the invention, base plate 720 is used to control the deformation of the blood vessels of the anastomosis. In one example, base plate 720 is prestressed to a desired diameter which is smaller or lager than the current diameter. In another example, base plate 720 acts against undue expansion of the blood vessel. In an exemplary embodiment of the invention, the diameter of the anastomosis is selected to allow enough blood to flow both downstream (e.g., in a coronary vessel tree) and upstream (to possible collateral vessels).

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In an exemplary embodiment of the invention, the circumference of base plate 720 increases or decreases by 5%, 10%, 20% or any smaller larger or intermediate percentage. Optionally, aperture elements 722 also provide a clip function, for example, as described above.

Fig. 7D is a partial cut-away view showing base plate 720 during exemplary deployment (some parts removed for clarity and some parts shown covering only part of base plate 720, instead of all the base plate). An optional spacer 740 is provided, that includes tabs 742 for preventing motion of bar 730 (not shown), while allowing motion of tabs 728 and passage of the puller. A cutting plate 744 having a plurality of apertures 746 provides a strong base against which the pullers can be sheared by retraction. Fig. 7E, also a partial cut-away view, shows the addition of an optional holder 750 which prevents base plate 720 falling into the body. After the anastomosis is started or completed, holder 750 is pulled back. In one example, holder 750 is hinged and it unfolds. In another embodiment, holder 750 is distorted by the retraction. In another embodiment, holder 750 is pulled out radially.

Figs. 8A-8D illustrate an extendible delivery system 800 in accordance with an exemplary embodiment of the invention, in which the actual delivery of a connector is performed by a modular capsule 802. A similar design may be used for other types of anastomosis delivery systems and/or for other endoscopic activities, such as punching holes and suturing. A potential advantage of such a modular design is that a same system can be used for different surgical approaches and methods, for example, endoscopic, key-hole and open chest. Another potential advantage is that a single handle can be used for multiple parts of a procedure, reducing the size and/or number of components in a kit.

In an exemplary embodiment of the invention, any endoscopic tool that is activated using rotation, retraction or advancing of a rod can be made modular by providing a suitable coupling for the power and control mechanism. Typically, both power and control are provided by a same element.

Fig. 8A shows a connector capsule 802 including a connector 804 as described in Figs. 7B-7E, an aperture 806 for insertion of a blood vessel and including an optional spilt for splitting the capsule for removal after the anastomosis is performed. A locking mechanism 810 is provided for locking to the rest of the delivery system and a rod extension 808 is provided to transfer retraction from the handle (Fig. 8B) to retract the pullers. Extension 808 may be polygonal or slotted, to support rotation. In other connector types, advancing of the connector or retraction of an over tube may be practiced instead, for example. Optionally, capsule 802

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includes a power train for changing displacement amounts to allow a same handle to be used with different capsules that require different amounts and/or directions of motion. Alternatively or additionally, the handle includes such a power train and/or includes means for allowing both retraction and advancing.

Fig. 8B shows a complete system 800 including capsule 802 coupled via a coupler 814 to a handle segment 812. Optionally, a retraction indicator 816 is provided on the handle to indicate a degree of retraction. In an alternative embodiment, reference 816 indicates a locking switch.

Fig. 8C illustrates an extender 820 that fits between coupler 814 and capsule 802. A part of capsule 802 is also shown coupled to a coupler 826 that corresponds to coupler 814 in Fig. 8B. A shaft 824 serves to extend the reach of the device and terminates in a rod extension 822, corresponding to extension 808 of Fig. 8A. Shaft 824 may be rigid, or it may be partly or completely flexible or hinged, at one or more points along its length. Optionally, shaft 824 is deformable, for example like a goose-neck. Optionally, shaft 824 includes a channel or slot (not shown) to act as a working channel, for example, to provide a camera, light source, material or tool to the tip of system 800. Such a channel is optionally provided also in handle 812 and/or in the capsule.

Fig. 8D shows a complete extended system.

Optionally, system 800 is used for an anastomotic connection in which leakage of blood is to be prevented after hole punching. In an exemplary embodiment of the invention, a shaft 850 including a homeostatic valve 856 (e.g., a leaflet valve) is used as a guide for punching and anastomosis delivery. In one exemplary implementation, a punch capsule is provided through a bore 854 of shaft 850. After the hole is punched, narrowing 852 is advanced over the punch into the holed blood vessel. The punch is then retracted and blood leakage is prevented or reduced by valve 856. A device delivery capsule (e.g., like capsule 802) is then provided through bore 854 and used to perform the anastomosis. Optionally, shaft 850 includes an axial tear line (not shown, for clarity) so that it can be torn off of the delivery system once capsule 802 is in place. Shaft 854 may be, for example short, like a capsule or long enough to reach outside the body.

In an exemplary embodiment of the invention, the above devices are used in combination with anastomosis-related tools as described in PCT applications and publications WO 99/62415, WO 00/56226, WO 00/56228, WO 01/41623, WO 01/41624, PCT/IL01/00267, PCT/IL01/00069, PCT/IL01/00074, PCT/IL01/00266 and a PCT application

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filed on even date with the instant application, in the Israel receiving office, by the same assignee and having attorney docket number 088/02281, the disclosures of which are incorporated herein by reference. However, they may also be used as stand alone devices or as part of surgical kits for other uses and/or anastomosis connectors.

It will be appreciated that the above described methods and devices of vascular manipulation may be varied in many ways, including, changing the order of steps, the exact materials used for the devices, which vessel is a "side" side and which vessel (or graft) is an "end" side of an end-to-side anastomosis and/or whether the end vessel is everted over the connector. Further, in the mechanical embodiments, the location of various elements may be switched, without exceeding the spirit of the disclosure, for example, switching the moving elements for non-moving elements where relative motion is required. In addition, a multiplicity of various features, both of methods and of devices have been described. It should be appreciated that different features may be combined in different ways. In particular, not all the features shown above in a particular embodiment are necessary in every similar exemplary embodiment of the invention. Further, combinations of the above features, from different described embodiments are also considered to be within the scope of some exemplary embodiments of the invention. In addition, some of the features of the invention described herein may be adapted for use with prior art devices, in accordance with other exemplary embodiments of the invention. The particular geometric forms used to illustrate the invention should not be considered as necessarily limiting the invention in its broadest aspect to only those forms, for example, where a circular lumen is shown, in other embodiments an oval lumen may be used.

Also within the scope of the invention are surgical kits which include sets of medical devices suitable for making a single or a small number of anastomosis connections and/or apertures. Measurements are provided to serve only as exemplary measurements for particular cases, the exact measurements applied will vary depending on the application. When used in the following claims, the terms "comprises", "comprising", "includes", "including" or the like means "including but not limited to".

It will be appreciated by a person skilled in the art that the present invention is not limited by what has thus far been described. Rather, the scope of the present invention is limited only by the following claims.

CLAIMS

- 1. An anastomotic connector comprising:
- a plurality of clip segments interconnected by a plurality of twistable resilient segments.
 - 2. A connector according to claim 1, wherein said segments are bendable out of a plane defined by said clip segments.
- 10 3. An anastomotic connector comprising:

a plurality of clip segments each defining a clip contact area where opposite sides of the clip engage tissue, interconnected by a plurality of attachment segments, wherein said attachment segments define a first circumference and said contact areas define a second circumference and wherein said two circumferences are not on a same plane.

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For the applicant,

Fenster & Co. Patent Attorneys, Ltd.

c:088/02291

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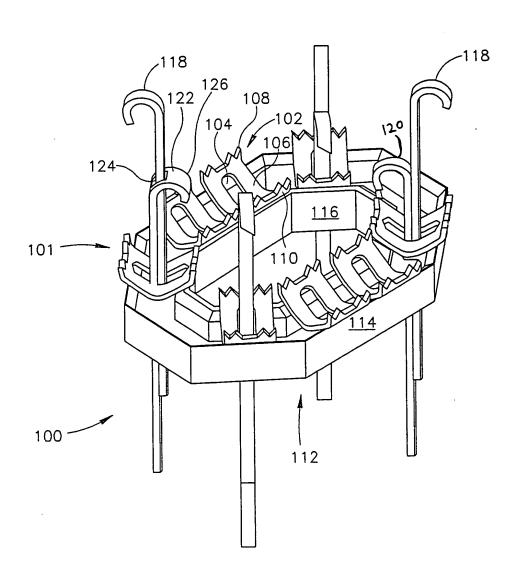


FIG.1



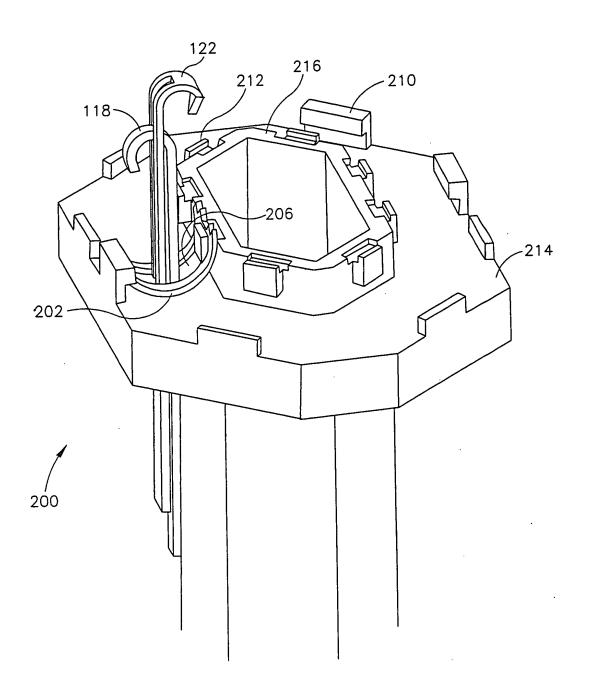


FIG.2

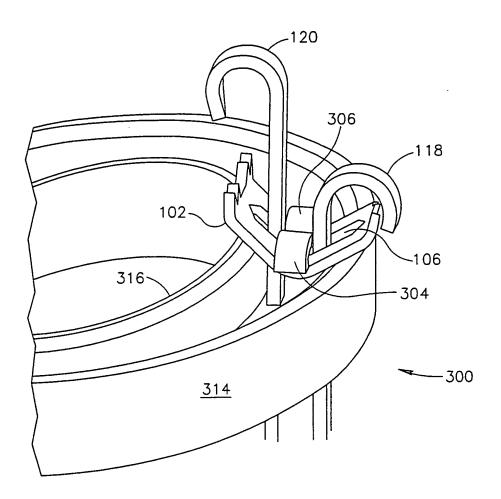
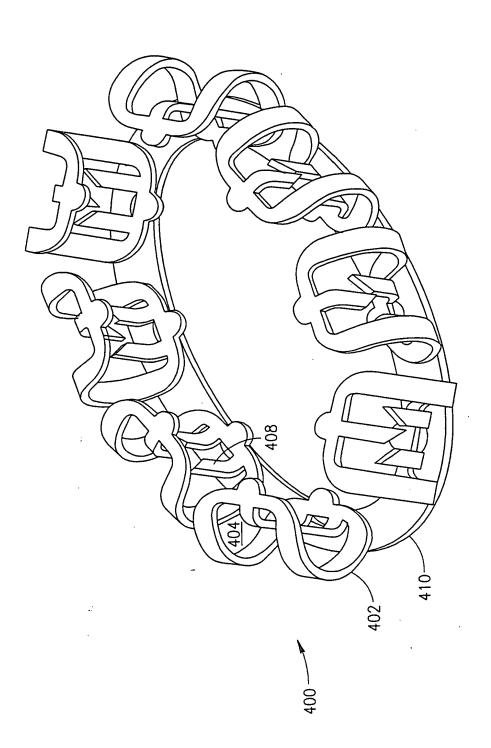


FIG.3





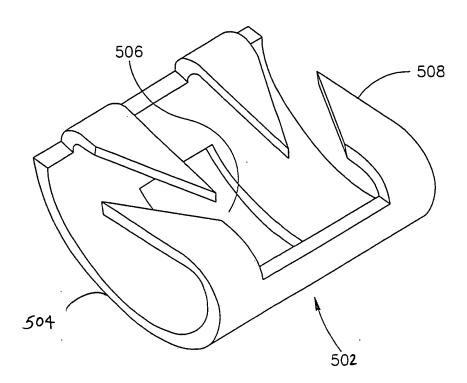


FIG.5

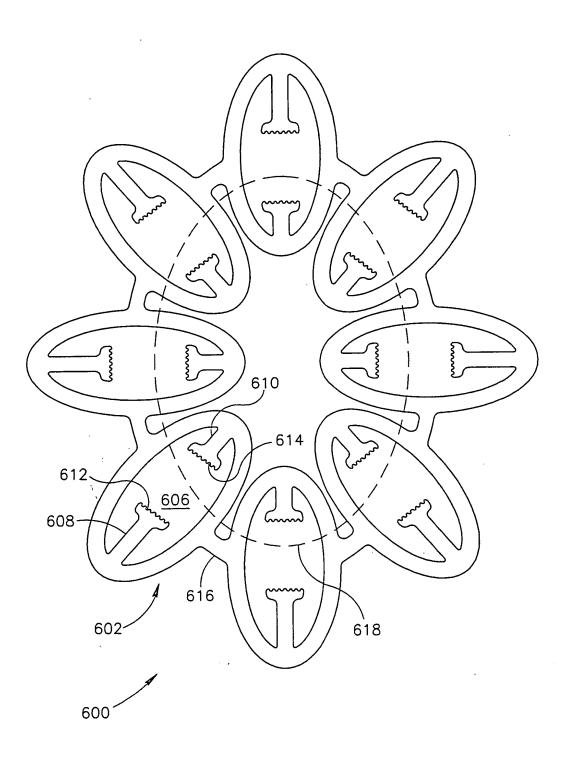


FIG.6A



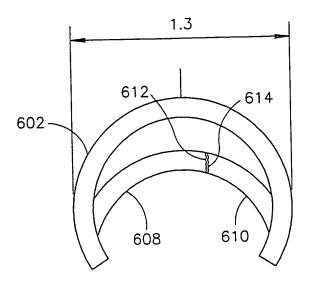


FIG.6B



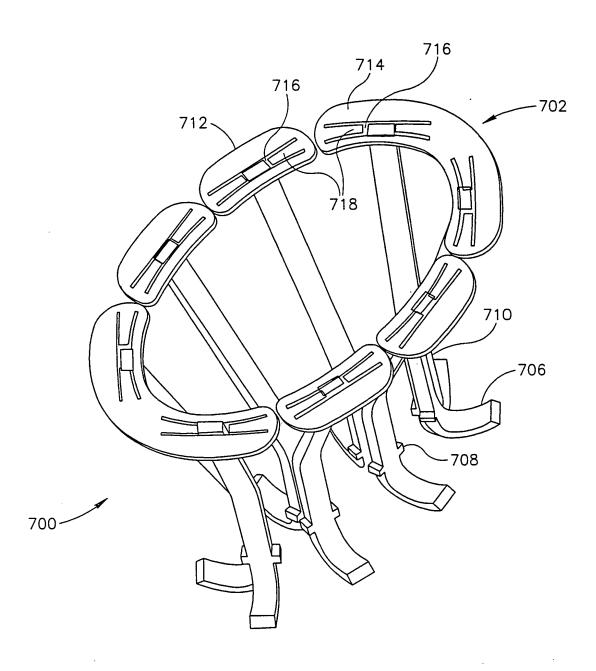
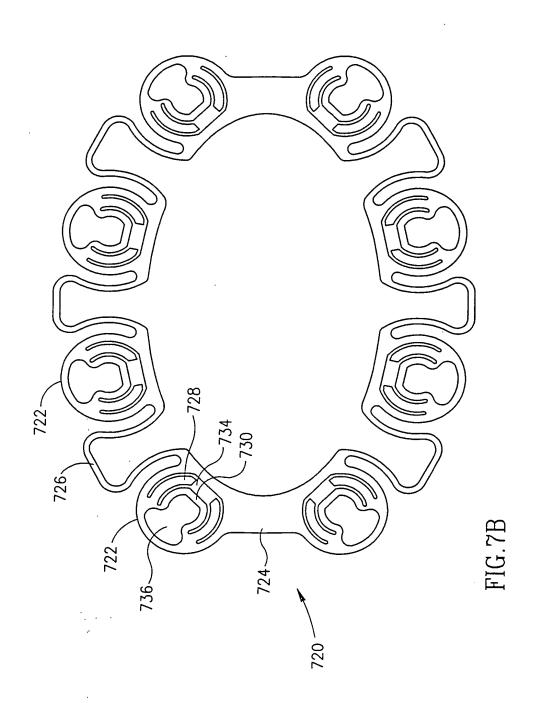
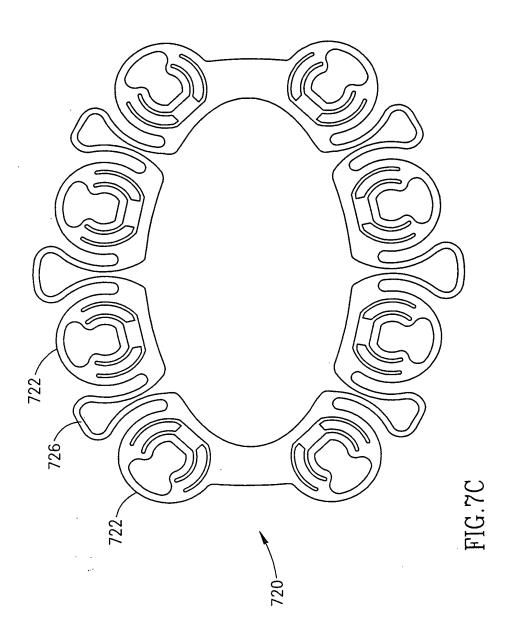


FIG.7A







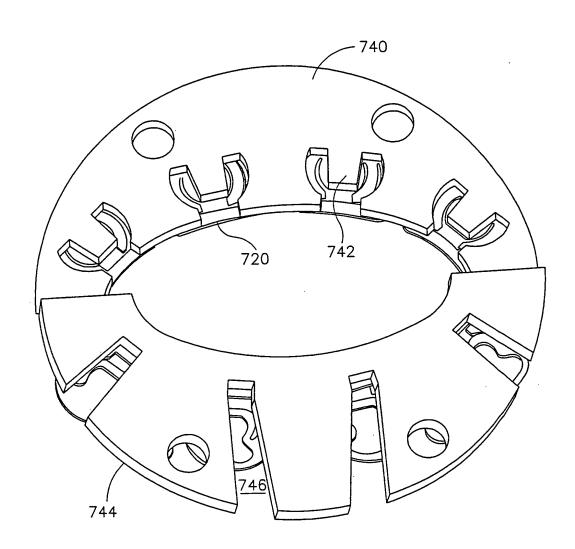


FIG.7D

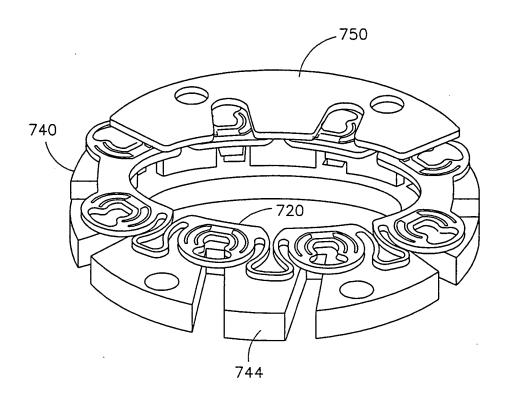


FIG.7E



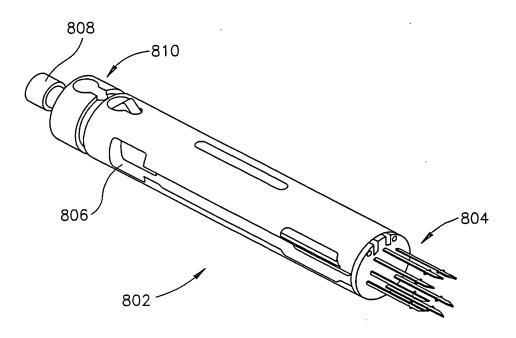
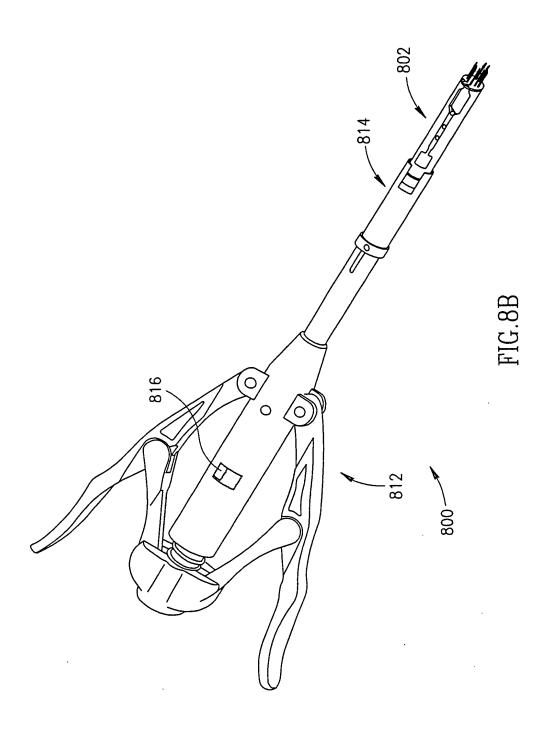


FIG.8A





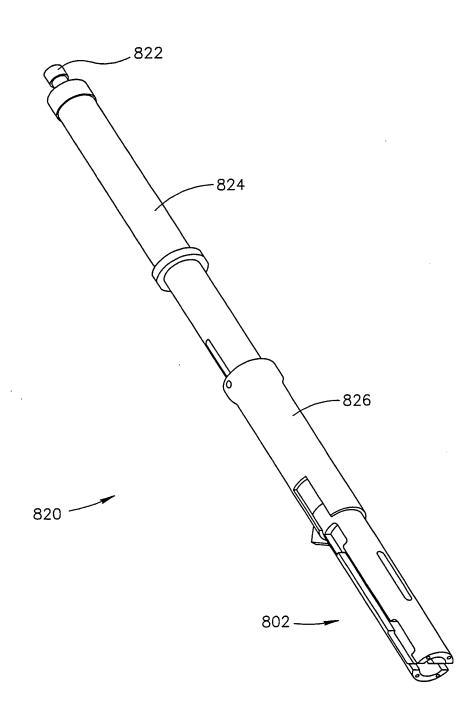


FIG.8C



